

Article - Health - General

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§21-239.

(a) (1) For purposes of §§ 21-207(b)(3), 21-216(b)(2), and 21-230(b)(5) of this subtitle, regarding food, drugs, and cosmetics respectively, the use of any added poisonous or otherwise deleterious substance, any food additive, or any color additive is considered unsafe unless the use of the substance or additive for the particular purpose is authorized by and the quantity of the substance that may be used for that purpose is limited by:

(i) A State adopted federal rule or regulation, as provided under subsection (b) of this section; or

(ii) A rule or regulation adopted by the Secretary under subsection (c) of this section.

(2) If a food, drug, or cosmetic contains any added poisonous or otherwise deleterious substance, any food additive, or any color additive in a quantity that is allowed by a rule or regulation as provided by paragraph (1) of this subsection, the food, drug, or cosmetic may not be considered adulterated because it contains that substance or additive.

(b) Subject to the provisions of § 21-241 of this subtitle, any rule or regulation that regulates the use of a food additive or a color additive and that is adopted by the federal government under the federal act automatically is adopted as a rule or regulation of this State.

(c) Whether or not in accordance with any rule or regulation that sets tolerances under the federal act and if public health or other considerations in this State make it necessary, the Secretary may adopt a rule or regulation that:

(1) As to any added poisonous or otherwise deleterious substance, any food additive, or any color additive:

(i) Prohibits its use; or

(ii) Sets tolerances for its use; or

(2) As to any food additive or any color additive:

(i) Sets conditions under which it may be used safely; or

(ii) Provides exemptions for its use for investigational or experimental purposes.

(d) (1) The rule or regulation may be adopted by the Secretary either on the Secretary's own initiative or on the petition of any interested party.

(2) Before the Secretary may adopt the rule or regulation on the basis of a petition, the petitioner shall establish by information that is submitted to the Secretary that the rule or regulation is needed and that the effect of the rule or regulation will not harm the public health.

(3) If the information submitted by the petitioner is not sufficient to allow the Secretary to determine whether, under the standards set forth in subsection (e) of this section, the rule or regulation should be adopted, the Secretary may require that additional information be submitted. Failure by the petitioner to comply with the Secretary's request is a sufficient ground to deny the petition.

(e) The Secretary, in determining whether to adopt a rule or regulation under this section, shall consider:

(1) The name of and all pertinent information that concerns the substance or additive, including, if available:

(i) Its chemical identity and composition;

(ii) The conditions of its proposed use, including directions, recommendations, and suggestions;

(iii) Samples of the proposed labeling for the substance or additive; and

(iv) All relevant information bearing on the physical or other technical effect of the substance or additive and the quantity of the substance or additive that is required to produce the effect;

(2) The probable composition of any substance that may be formed in or on a food, drug, or cosmetic as a result of the use of the substance or additive;

(3) The probable amount of the substance or additive that would be consumed in the average human diet, taking into account any chemically or pharmacologically related substance in the diet;

(4) Safety factors that, in the opinion of experts qualified by scientific training and experience to evaluate the safety of the substance or additive for its proposed use, are generally recognized as appropriate for the use of animal experimentation information;

(5) The availability of a practicable method of analysis for determining the identity and quantity of:

(i) The substance or the additive in or on an article;

(ii) Any other substance that is formed in or on the article because of the use of the added substance or color additive; and

(iii) The pure substance or additive and any intermediate or impurity of the substance or additive;

(6) Any fact that supports a contention that the proposed use of the substance or additive would serve a useful purpose; and

(7) Any other factor that is relevant to the issues of whether there is a need for the use of the substance or additive or whether the use would harm the public health.

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